IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION	

REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DR. MARC TOGLIA

In further support of their Motion to Limit or Exclude Certain Opinions of Marc Toglia, M.D. ("Dr. Toglia"), Plaintiffs state as follows:

ARGUMENT

I. Plaintiffs' arguments apply to all products upon which Dr. Toglia has provided opinions—they are not limited to just the TVT.

As an initial matter, at several points in its response brief, Ethicon asserts that Plaintiffs' arguments "appear" to only be directed at Dr. Toglia's opinions relating to the TVT device. *E.g.* Def's Brf. at 3, 13, 17. That is not correct. Dr. Toglia did sit for separate depositions—one regarding TVT, and one regarding Prolift and Gynemesh PS, but for the purposes of this *Daubert* motion, the testimony that he gave at both those depositions is relevant and applicable to his opinions, regardless of the product at issue in a particular case.

In fact, there was an agreement not to duplicate testimony on overlapping issues in the depositions—and Ethicon specifically enforced that agreement during Dr. Toglia's Prolift and

Gynemesh PS deposition.[1] As such, there was no opportunity—let alone a requirement—for Plaintiffs' counsel to duplicate all of their questioning in each of Dr. Toglia's depositions. And even in the absence of such an agreement, the arguments in Plaintiffs' Motion relate to the general lack of scientific reliability of Dr. Toglia's opinions; a failure that serves to preclude his similar opinions regarding all vaginal mesh devices—*e.g.* degradation and immunologic response, the properties of polypropylene, complication rates, instructions for use (IFUs)—not simply the TVT. Simply put, Plaintiffs' arguments apply to Dr. Toglia's opinions regardless of the product at issue in a particular case.

II. Dr. Toglia's opinions are duplicative, unreliable, and would not assist the jury.

Dr. Toglia's opinions far exceed his qualifications, he was unable to support them at deposition with any literature or evidence, and his opinions based on his own clinical experience are admittedly based on speculation. His opinions should be barred as explained below.

A. Dr. Toglia's testimony regarding his own clinical experience and "success rate" is unsupported by factual evidence.

Ethicon has not shown, and cannot show, that Dr. Toglia's clinical experience is reliable or that is perceived complication rate is factually supported. Ethicon claims that Dr. Toglia used a spreadsheet to track his complication rate. Def's Brf. at 5. However, when asked if the spreadsheet could be produced, Dr. Toglia responded that he was unsure it was used past a certain time period and that he does not have the spreadsheet:

> **Q**. Did I hear you correctly that you track your complications in your practice using mental notes?
> . . .
> THE WITNESS: We track our complications on – on spreadsheets, on paper.
> **Q**. And we could request those spreadsheets and papers that track your complications?
> **A**. I don't know that those exist beyond a certain period of time. They're not published.
> **Q**. And you don't have those in your office that we can look at?

[1] Ex. E to Motion (referred to herein as "Ex. E"), 20:10-11, 22:23-24:5.

A. I'm sorry, I do not.[2]

Dr. Toglia was given repeated opportunities to explain how he arrived at his clinical complication rate, and repeatedly answered that he would have to go through the records of his patients to verify and that these records, along with his alleged spreadsheet, are unavailable to him or unable to be produced, and he cannot distinguish the complications he has seen in his practice across the various products he has seen and used.[3] Dr. Toglia insists upon relying upon only "Level 1" evidence, except when it comes to the data used to form his own complication rate, which Dr. Toglia admits has never been published and therefore never subjected to any peer review.

Furthermore, Ethicon's assertion that Dr. Toglia can rely on the published literature of others to support conclusions about his own clinical experience is unfounded. Def's Brf. at 4-5. Other studies, by other physicians, about other patients, cannot support or prove what has occurred in Dr. Toglia's own patient population.

Finally, Dr. Toglia's own testimony regarding his clinical experience does not satisfy Rule 702's most basic requirements: "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."[4] Dr. Toglia repeatedly failed to do this at his deposition and his testimony regarding his rates of complication with the TVT device at issue in this litigation in his should be excluded.

[2] Exhibit D to Motion (referred to herein as "Ex. D"), 413:12-414:5.
[3] *Id.*, *see also* 65:22-24, 66:1-67:23, 69:12-21, 161:18-162:10, 165:1-166:22.
[4] *See* FED. R. EVID. 702 advisory note

B. Dr. Toglia is not qualified to give opinions on polypropylene safety, durability, biocompatibility, MSDS and materials, and he has no reliable methodology to support those opinions.

Ethicon's response again cites to Dr. Toglia's resume and report but fails to address Dr. Toglia's admitted shortcomings in his deposition. Despite Dr. Toglia's "experience in the field of biomaterials,"[5] and being a paid consultant for Ethicon on various of their devices, the fact remains that Dr. Toglia could not opine on clinically significant aspects of the polypropylene materials used in the devices at his deposition including:

- Dr. Toglia's inability to properly identify the mesh as being heavyweight despite allegedly relying on documents and literature which clearly identify it as such;[6]
- Ignorance of the fact that mesh weight is used by experts in the field to classify surgical mesh;[7]
- Ignorance as to the type of polypropylene material used in other pelvic products, despite being involved in their development;[8] and
- Ignorance as to the additives used to make Prolene, and failure to even inquire as to what those additives may be.[9]

Dr. Toglia further disqualified himself by testifying that many of these things were not relevant or reliable to him or on the levels of evidence to which he would even consider in forming his opinions.[10]

Plaintiffs do not "fail to understand" Dr. Toglia's testimony on the issue of lightweight mesh. A plain reading of his testimony makes clear that Dr. Toglia is unaware of the meanings of

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[5] Def's Brf. at 8.
[6] Ex. E at 54:1--58:3, *see also* Exhibit B to Motion, Expert Report of Dr. Marc Toglia at 9, 25, 48 (citing to various articles on mesh weight classification and its clinical significance).
[7] Ex. E at 56:5-8.
[8] *Id.* 54:1-55:5, 72:5-14; 74:4-24.
[9] *Id.* at 144:16-146:8.
[10] *Id.* at 260:9-19 (if deformation caused device to no longer fit his macroporous classification, he would not want to know because that is not "relevant."), 360:11-23 (MSDS is not reliable); 238:23-24 (MSDS "is non-clinical regulatory type stuff.").

the terms "lightweight" and "heavyweight" as used in regard to mesh. Furthermore, Ethicon's arguments on this point only undercuts Dr. Toglia's qualifications to testify in this regard. Indeed, Ethicon's multiple references to documents which discuss "lightweight" mesh only support Plaintiffs' argument. Ethicon cites to the AUGS-SUFU position statement—a document Dr. Toglia discusses at length in his deposition[11]—and yet he still struggles over what the term "lightweight" means or even recognize that AUGS, a group to which he is a member,[12] regularly uses that terminology to describe the properties of midurethral slings.

Dr. Toglia's opinions on these topics which he unqualified to give are not based on any reliable methodology or literature that Dr. Toglia can point to and should therefore be excluded.

C. Dr. Toglia is not qualified to testify about the complication rates and risks associated with the Burch and autologous fascial sling procedures.

Again Ethicon attempts to rely on Dr. Toglia's resume to support his opinions on the complication rates and risks associated with the Burch and autologous fascial sling procedures. Def's Brf. at 10-12. Dr. Toglia was offered ample time off the record (at his request) to find any published literature supporting the opinions regarding these issues during his deposition and could not do so. [13] Dr. Toglia's opinions on this topic should be excluded.

E. Dr. Toglia relies on circular logic for his opinions regarding degradation and immunologic response, and cannot cite to reliable scientific evidence to support his opinions.

At his deposition, Dr. Toglia was clearly asked whether he was aware of any studies which show that the polypropylene mesh used in Ethicon's devices does not degrade. Dr. Toglia responded that he was "not aware of any concerns that there might be degradation that would

[11] Dr. Toglia discusses the AUGS/SUFU position statement at length in his deposition, Ex. D. at 41:18-24, 45:18-51:4, 197:22-14; 330:13-333:2.
[12] See CV of Dr. Marc Toglia, attached to the Report of Dr. Marc Toglia, Ex. B to Motion.
[13] Ex. D at 120:3-121:18.

prompt one to do those kinds of studies."[14] As pointed out in Plaintiffs' Motion, Dr. Toglia could find no literature to support his opinion on degradation and immunological response, if any, caused by the devices. Dr. Toglia is simply sure degradation does not exist, and doesn't believe there would be any clinical effects of degradation.[15] This is not the kind of reasoning or methodology that qualifies as reliable under *Daubert*. Dr. Toglia's opinions regarding degradation and the body's immunologic response to the devices are unsupported by any factual evidence or reliable methodology and must therefore be excluded.

F. Dr. Toglia's opinions on the Instructions for Use ("IFU") and warnings are not based on a reliable methodology.

Dr. Toglia testified at his deposition that he could not comment on certain portions of the IFU because he did not know their context.[16] Dr. Toglia was clear when he testified that to him the IFU are "instructions on how the product is to be used"—nothing more.[17] Dr. Toglia could also not offer an opinion on whether or not the IFU provides a complete and accurate listing of all potential risks associated with the product. If Dr. Toglia cannot understand these aspects of the IFU, how can he possibly offer an opinion as to their adequacy or comment on the warnings contained therein? If Dr. Toglia cannot answer questions about the IFU because he is "not familiar with the context"[18] of statements made within it, how can he possibly opine on them as an expert? He cannot. Dr. Toglia's testimony and opinions regarding the IFU are not based on a reliable methodology and fail to pass muster under *Daubert* and should be excluded.

[14] *Id*. at 137:2-138:17.
[15] *Id*. at 140:9-13, 148:6-9, 139:23-140:7.
[16] *Id*. at 284:20-285:23.
[17] *Id.* at 280:2-9.
[18] *Id.* at 284:14-285:23.

CONCLUSION

For the foregoing reasons, Dr. Toglia's opinions do not meet the requirements for admission under *Daubert* and FED. R. EVID. 702, 403 and 104. Accordingly, his opinions in this case must be excluded, or at least limited.

Dated: May 16, 2016

By: /s/ Edward A. Wallace

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Edward A. Wallace